REMARKS

In the last Office Action mailed February 3, 2009, claims 26, 27, 30, 31, 33, 34 and 36-47, were all rejected under 35 U.S.C. 112 and 101. In addition, claims 26, 27, 30 and 43-45 were rejected under 35 U.S.C. 102 and claims 31 and 34 were rejected under 35 U.S.C. 103(a). Reconsideration of the rejections is respectfully requested in view of the amendment of independent claim 26 and many of the dependent claims.

The 35 U.S.C. 112 Rejection

Claim 26 was rejected as failing to "particularly point out and distinctly claim" for failure to provide an antecedent basis for the limitation "the program". In order to overcome this rejection, the preamble has been amended so to recite a program which "includes at least one deployed automated external defibrillator having a replaceable battery and electrodes for resuscitating a cardiac arrest victim." It is believed that this amendment of claim 26 should overcome the 35 U.S.C. 112 rejection and reconsideration is respectfully requested.

The 35 U.S.C. 101 Rejection

All of the pending claims have been rejected for failure to recite a method or "process" which is either "tied to a particular machine or apparatus" or "transforms a particular article to a different state or thing" citing *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U. S. 584, 588 n. 9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *In re Bilski*, 545 F. 3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008).

Reconsideration of the Section 101 rejection is respectfully requested in view of the extensive amendments to the claims so as to clearly and extensively tie the claimed method to a specifically recited machine. More specifically, claim 26 now recites a plurality of method or process steps for auditing and certifying an existing cardiac emergency readiness program including at least one "automated external defibrillator" where each step recites and is tied to a "defibrillator". Clearly, an automated external defibrillator is a "machine" within the meaning of the above-cited cases and the steps of the method are extensively and inextricably "tied" to that "machine".

Although statutory subject matter required by 35 U.S.C. 101 is clearly recited in claim 26 because the method is extensively tied to a machine comprising an automated external defibrillator, claim 26 is also statutory since a method is recited which meets the "transformation" prong of the "machine-or-transformation " test as articulated by the court in *In re Bilski.* Claim 26 recites a hmodification to a facility's cardiac emergency readiness program. More specifically, specific physical modifications at the facility are recited including "the number and location of, the battery and electrodes for, and the personnel who are trained and certified to use defibrillators".

The Section 35 U.S.C. 102 Rejection

As stated above, claim 26 has been extensively amended to recite a method for auditing and certifying a facility's "existing" cardiac emergency readiness program including "at least one deployed automated external defibrillator". Reconsideration of the 35 U.S.C. 102 rejection is respectfully requested since the prior art fails to disclose the concept of supporting or maintaining an existing cardiac emergency readiness program including an already deployed defibrillator let alone the specific auditing and certifying steps recited in claim 26.

The Altman reference relied upon by the Examiner deals with the initial implementation of a cardiac emergency readiness program including an automated external defibrillator but is in no way concerned with the ongoing support of that program let alone auditing and certifying the program after the initial implementation. For example, Altman does not even mention that the defibrillators are powered by a battery which must be monitored or "audited" and periodically replaced. While the electrodes of the defibrillator are mentioned, there is no indication that the electrodes must also be monitored or "audited and periodically replaced. In fact, the Examiner concedes that Altman does not disclose the "review" or other monitoring of defibrillator maintenance. Similarly, there is no recognition by Altman that training and certification of on-site personnel in defibrillator usage must be monitored or "audited" since the availability of such personnel is not static, i.e., there is personnel turnover and training certifications expire. Finally, there is no recognition by Altman that defibrillators in an existing program may not be maintained in the proper

locations and locations of defibrillators must therefore be monitored or "audited". Even if Altman does recognize that a facility survey should be initially performed to assure that a defibrillator is within a predetermined proximity of any sudden cardiac arrest victim (and this is far from inherent let alone express*), there is no recognition or suggestion that the locations of the defibrillators should in any way be monitored or "audited" to be sure that defibrillators were actually placed or remain in the locations determined by a proper survey.

The Altman reference is totally devoid of any teaching regarding the certification of the cardiac emergency readiness program including at least one deployed defibrillator. Although the Office Action makes reference to the phrase " 'Universal Access to Defibrillation' statutes that require completion of a certification or training program" in Altman and then contends that the word "certification" applies to a program including a defibrillator, the contention is without foundation. In Altman, the word "certification' only appears in the answer to the question: "8. What training is needed to use AEDs?". The word "certification" is therefore only used with reference to certifying persons who receive "AED" training which is provided by organizations like "AHA, National Safety Council and American Red Cross. The certification recited in the claims to the extent it involves trained personnel involves the certification of the overall program including the "number of currently trained and certified" personnel at a facility but not the certification of their training which is provided by organizations like AHA. Neither Altman nor any statute in existence in 1999 can be fairly read to disclose or suggest the certification of a cardiac emergency readiness program employing a defibrillator let alone certifying the specific requirements recited in the claims.

For all of the reasons stated above, reconsideration and withdrawal of the 35 U.S.C. 102 rejection is respectfully requested.

* The Office Action in contending that Altman discloses proper placement of defibrillators apparently relies exclusively on the following statement: "AED programs consider how many devices a company needs." There is however no indication of how that number is arrived at. Is it the number of facilities a company has? Is it the number of employees a company has a particular facility? Is it the nature of the activities at a facility? It is respectfully suggested that hindsight must be relied upon to conclude that this language "inherently includes" a survey to determine the proper locations of defibrillators within a facility to assure a predetermined proximity to a victim of sudden cardiac arrest.

The 35 U.S.C. 103 Rejection

The subject matter of claim 31, which was rejected as obvious under 35 U.S.C. 103, is now incorporated in independent claim 26. This rejection was based on Altman in combination with the PAED reference. Although the Examiner contended that PAED disclosed "reviewing maintenance" of defibrillators and the use of such a review or audit as now recited in claim 26 would have been obvious in the method of Altman,, it is respectfully submitted that PAED contains no such disclosure. As a result, and the claimed method now recited in amended claim 26 could not therefore be obvious.

PAED is devoid of any maintenance review or any suggestion that such a review is necessary. There is not even any mention of batteries or electrodes let alone the requirement for replacement and "auditing" replacement.. The Examiner apparently relies upon a reference to "quality assurance" performed by the "designated physician" of a Regional Emergency Medical Advisory Committee including "periodic retraining and assessment of the service" as well as requirement to identify by make and model the defibrillators "they plan to use". The nature of the "quality assurance" described explicitly requires the physician to review incidents where the defibrillator was used to care for patients and provide "periodic retraining and assessment of the service." There is no further explanation of what is meant by this and certainly no suggestion that it is in anyway related to maintenance of the defibrillators let alone the replacement of batteries and electrodes..

Even assuming that PAED discloses an "auditing" of training to be used by the "designated physician" (and not instruction of the EMS personnel by the "designated physician" as the language including the word "provide" seems to suggest), there is no indication that there is an auditing of the number of trained and certified personnel at a particular facility or even in a particular EMS ambulance. Nor is there any indication that the physician is required to audit or in anyway monitor the locations of defibrillators. Finally, the mere identification of defibrillators which the physician "plans" to use in the future in no way suggests any plan to follow-up on the maintenance of the defibrillators, especially given the failure to even mention batteries and electrodes.

Since Claim 26 as amended distinguishes over the prior art and clearly recites patentable subject matter, a prompt allowance of claim 26 and the dependent claims is respectfully requested.

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